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10/626,069	07/24/2003	Garret D. Cawthon	37013-6	9758

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EXAMINER

LAMM, MARINA

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

## Application No.

10/626,069

## Applicant(s)

CAWTHON, GARRET D.

## Examiner

Marina Lamm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 39-73 is/are pending in the application.
- 4a) Of the above claim(s) 61-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 7/24/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 61-73 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/18/04.
2. Claims 39-60 are being examined at this time.

### ***Claim Objections***

3. Claim 50 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 50 recites the limitation "wherein the fluid base material comprises cod liver oil". The claim fails to further limit the subject matter of Claim 39, from which it ultimately depends, because Claim 39 recites that a fluid base material is selected from mineral oils, silicone oils, plant-based oils, water and mixtures thereof. The cod liver oil recited in Claim 50 does not fall in any of these categories of the fluid base material since it is a fish-derived oil.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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*Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 39-60 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of U.S. Patent No. 6,627,178 ('178). An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 39-60 are generic to all that is recited in claims 1-30 of '178. That is, Claims 1-30 of '178 fall entirely within the scope of claims 39-60 of the instant invention, or, in other words, Claims 39-60 are anticipated by Claims 1-30 of '178. Specifically, the both inventions are directed to a method for treating diaper rash comprising the same steps. The specific composition recited in '178 anticipates the generic composition recited in the instant claims.

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***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 39, 40, 44-48 and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245).

Adams et al. teach diaper rash aerosol composition containing about 70% of water, jojoba oil and macadamia oil. The recitation of viscosity that is "sufficiently low to allow the composition to be atomized" is inherent in the reference because the reference teaches compositions in the form of aerosols. The Adams et al. reference does not teach the component (2) of the instant claims. However, Clark et al. teach topical barrier composition containing 1-40% of micronized zinc oxide which has a mild astringent, protective and antiseptic action. See col. 7, lines 5-23. The compositions of Clark et al. also contain a silicone material such as dimethicone or cyclomethicone, kaolin, calamine or talc, and petrolatum and/or mineral oils. See col. 2, lines 61-67; col. 3, lines 10-14; col. 5, lines 16-35. The compositions of Clark et al. provide a superior, long-lasting protective barrier formulation for managing diaper rash. See col. 4, lines 45-59. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Adams et al. such that to use zinc oxide and/or silicone oils and/or mineral oils. One

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having ordinary skill in the art would have been motivated to do this to obtain long-lasting skin protective formulation as suggested by Clark et al. With respect to Claims 54-56, the Adams et al. reference does not explicitly teach the claimed viscosity. However, the determination of optimal or workable viscosity by routine experimentation is obvious absent showing of criticality of the claimed viscosity. One having ordinary skill in the art would have been motivated to do this to obtain the desired sprayability of the composition.

8. Claims 39, 40, 44 and 54-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gebhart et al. (US 3,584,115) in view of Moss (US 4,816,254), supplied by the Applicant.

Gebhart et al. teach aerosol compositions for the treatment of skin irritations such as diaper rash containing sesame oil (or other plant-based oils), vitamins A and D, and other topical ingredients. See col. 1, lines 37-40; col. 6, lines 46-59; col. 7, lines 71-75; col. 8, Example 9. The compositions of Gebhart et al. form a film on the area being treated. See col. 3, lines 11-15. The recitation of viscosity that is "sufficiently low to allow the composition to be atomized" is inherent in the reference because the reference teaches compositions in the form of aerosols. Gebhart et al. do not teach the component (2) of the instant claims. However, Moss teaches compositions for the treatment of skin irritations such as diaper rash containing zinc oxide, which has antiseptic activity, and cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. See col. 2, lines 48-55; col. 3, lines 35-47. The

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compositions of Moss form protective water-repellent coating on the skin. See col. 2, lines 53-55. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Gebhart et al. such that to use zinc oxide. One having ordinary skill in the art would have been motivated to do this to obtain additional antiseptic effect as suggested by Moss. Alternatively, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Gebhart et al. such that to use cod liver oil instead of vitamins A and D. One having ordinary skill in the art would have been motivated to do this because cod liver oil contains vitamins A and D and promotes rapid, scar-free healing as suggested by Moss. With respect to Claims 54-56, the Gebhart et al. reference does not explicitly teach the claimed viscosity. However, the determination of optimal or workable viscosity by routine experimentation is obvious absent showing of criticality of the claimed viscosity. One having ordinary skill in the art would have been motivated to do this to obtain the desired sprayability of the composition.

9. Claims 41-43, 59 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245) and further in view of Boussouira et al. (US 6,103,247).

Adams et al. in view of Clark et al. applied as above. While teaching that the particle size of zinc oxide should be such that the topical composition is smooth and homogeneous, the Clark et al. reference does not explicitly teach the particle size of the

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instant claims. However, Boussouira et al. teach using transparent zinc oxide having an average diameter of 1-500 nm in cosmetic composition because of its aesthetic appeal. See col. 5, lines 31-42. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of Adams et al. in view of Clark et al. such that to use transparent zinc oxide having an average diameter of 1-500 nm. One having ordinary skill in the art would have been motivated to do this to obtain aesthetically pleasing compositions as suggested by Boussouira et al.

10. Claims 39, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Mulder (US 5,536,502) and Moss (US 4,816,254), both supplied by the Applicant.

Adams et al. or Gebhart et al. applied as above. Neither reference teaches lanolin, petrolatum and cod liver oil of the instant claims. However, Mulder teach using petrolatum and lanolin as emollients in topical compositions for their soothing action by lubricating injured skin. See col. 4, lines 50-56. Further, Moss teaches compositions for the treatment of skin irritations such as diaper rash containing cod liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. See col. 2, lines 48-55; col. 3, lines 35-47. The compositions of Moss form protective water-repellent coating on the skin. See col. 2, lines 53-55. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of either Adams et al. or Gebhart et al.



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such that to use cod liver oil, lanolin and petrolatum. One having ordinary skill in the art would have been motivated to do this to obtain rapid, scar-free healing and soothing action of the composition as suggested by Moss and Mulder.

11. Claims 39, 51 and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Huffstutler (WO 92/06701).

Adams et al. or Gebhart et al. applied as above. Neither reference teaches calendula, chamomile or comfrey of the instant claims. However, Huffstutler teaches using comfrey extract in topical compositions for its healing properties and ability to stimulate epithelial development in the case of skin damage or breakdown. See p. 2, lines 13-14. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the aerosol diaper rash compositions of either Adams et al. or Gebhart et al. such that to use comfrey extract. One having ordinary skill in the art would have been motivated to do this to obtain improved healing properties as suggested by Huffstutler.

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Huffstutler (WO 92/06701) as applied to Claim 51 above and further in view of Moss (US 4,816,254).

Adams et al. or Gebhart et al. in view of Huffstutler applied as above. Neither reference teaches the ingredients of the instant claim. However, Moss teaches compositions for the treatment of skin irritations such as diaper rash containing cod

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liver oil, which provides the skin with vitamins A and D and promotes rapid, scar-free healing. See col. 2, lines 48-55; col. 3, lines 35-47. The compositions of Moss form protective water-repellent coating on the skin. See col. 2, lines 53-55. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the compositions of either Adams et al. or Gebhart et al. in view of Huffstutler such that to use cod liver oil. One having ordinary skill in the art would have been motivated to do this to obtain rapid, scar-free healing action as suggested by Moss.

### ***Conclusion***

13. No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

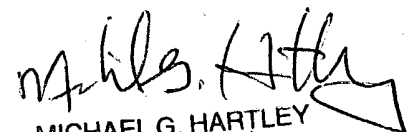
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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ml

11/19/04

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER